Boston Brace
20 Ledin Drive
Avon, MA 02322
T: 800.262.2235
T: 508.588.6060
F: 800.634.5048
F: 508.587.8119
www.bostonbrace.com

AUG 2 2 2011

510(k) Summary

The following summary is provided in pursuant to Section 513 (I)(3)(A) of the Federal Food, Drug and Cosmetic Act.

1) **Applicant Information**

- Applicant's Name and Address: Boston Brace International, Inc., 20 Ledin Drive, Avon, MA 02322, Telephone: (508) 588 – 6060, Fax: (800) 634 – 5048
- FDA Establishment Registration Number: 3001967835
- Contact: James H. Wynne, CPO, Vice – President, Director of Education, Telephone: (508) 588 – 6060, x-244
- Submission Correspondent: Same as Contact
- Summary Date – Oct 1, 2010

2) **Submission Information**

- Type: Traditional 510(k) Submission
- Proprietary Name: The Boston Band
- Common Name: Cranial Orthosis
- Classification: Class II (Special Controls); OAN, CFR 882.5970
- Classification Name: Cranial Orthosis
- Predicate Devices: STARband Cranial Remolding Orthosis - K082950
  Boston Band Cranial Remolding Orthosis - K072862
  Hanger Cranial Band – K072566

3) **Manufacturing Site:**

20 Ledin Drive, Avon, MA 02322, Telephone: (800) 262-2235,
Facsimile: (800) 634-5048

FDA Establishment Registration Number: 3001967835

4) **Device Description**

The Boston Band is a cranial orthosis used to treat abnormally shaped craniums in infants three to eighteen months of age. This condition is clinically known as Positional or Deformational Plagiocephaly. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened-areas of the skull into the created spaces to improve proportion and symmetry. The Boston Band is only available if prescribed by a physician. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

The Boston Band is essentially the same device as released by K072862. It is an orthosis designed for each patient from a cast or scan of the infant's head. The mold, either plaster from a cast, or foam, carved from the scan, is modified and prepared for fabrication according to the instructions provided by the treating practitioner using plaster/CAD modification techniques. Each orthosis is composed of an outer shell of thermoformable plastic, a single layer of ½ inch or 5-6 layers of 1/8 inch, or a combination of 1 – 2 1/4 inch layers with 1/8 inch layers of hypoallergenic polyethylene foam (Aliplast/Plastazote) and a strap for securing the orthosis. It has a top and side opening. Optimum fit and alignment is insured and monitored by the same clinical practitioner.

5) **Statement of Indications and Intended Use**

Statement of Indications:

The Boston Band is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Intended Use:

The Boston Band is design to treat infants with abnormally shape craniums from age three to eighteen months. It is available by prescription only. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. However, due to new surgical techniques for infants with craniosynostosis, post-surgical plagiocephaly, brachycephaly,and and scaphocephaly are a growing patient group.

6) **Summary of Technological Characteristics**

The proposed changes involve: A) expansion of the indications for use to include infants of the same age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads, B) how the infants head is captured (class of laser change), C) the method to modify the 3- dimensional (3D) mode (CAD vs. hand modification), D) the use of different thicknesses of the foam inner liner (both aliplast and plastazote) and E) the use of an updated carver machine that is an industry standard. There have been some minor changes to the original K072862 that were determined to not require a 510(k) submission. The overall design of the cranial orthosis will remain the same. The following table illustrates the minor differences between the cleared device (K072862) and the device as it is currently marketed.

Table 1 Comparison of Boston Band Cranial Remolding Orthosis (K072862) to proposed device: The Boston Band

Note: No changes will be made to the current device as a result of the proposed indications and shape capture change in this submission

Feature	Predicate Device K072862	The Boston Band
Intended Use	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes.	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Materials	- outer shell of thermoformable plastic (1/4 or 3/16 copolymer plastic) - - 5-6 layers of 1/8 inch hypoallergenic polyethylene foam (Aliplast) - Velcro strap (pile) sticky back Velcro hook	- outer shell of thermoformable plastic (1/4 or 3/16 copolymer plastic) - a single layer of ½ inch or 5-6 layers of 1/8 inch, or a combination of 1 – 2 1/4 inch layers with 1/8 inch layers of pelite hypoallergenic polyethylene foam or Aliplast - Velcro strap (pile) sticky back Velcro hook
Product Design	Cranial Orthosis –made to individual's specifications	Cranial Orthosis – made to individual's specifications
Production	-Model of the infants head from a negative impression (cast) of the infants head -Scan of the infants head from a Fastscan hands free class II laser scanner - Scan of the infants head using the Orthomerica Starscaner class I laser scanner - Foam model of the infants head carved using an industry standard 5 axis scanner	Model of the infants head from a negative impression (cast) of the infants head -Scan of the infants head from a Fastscan hands free class II laser scanner -Scan of the infants head using a Fastscan handheld class I laser scanner - Scan of the infants head using the Creaform class I laser scanner sold as Ohio Willow Wood Omega/handycam - Foam model of the infants head carved using an industry standard 5 axis scanner

Table 2 Comparison of Boston Band Cranial Remolding Orthosis (K072862) to proposed device: The Boston Band

Labeling	Predicate Device (K072862)	The Boston Band
Indications	Infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes	Same and to include the adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic, brachycephalic, and scaphocephalic shaped heads.
Contraindications	Infants with Craniosynostosis or hydrocephalus	Same
Warnings	Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of growth. Describe to caregiver steps that should be taken to reduce the potential restrictions of cranial growth and possible impairments to brain growth and development. A clinician or caregiver must evaluate the patient's skin at frequent intervals.	Same
Precautions	If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit it according to fitting instructions. Wear and care guide to be reviewed and provided to caregiver.(copy attached)	Same
Adverse Effects	This device may cause skin irritations or breakdown	Same
Instructions for Use	Wear and care guide provided to caregiver	Same
Expiration date	When the infant outgrows the cranial helmet or the orthosis is discontinued for any reason, the referring physician is contacted. If an other helmet is requested by the family to try to further correction, refer back to their physician for reevaluation and a new prescription.	Same

Table 3 Comparison of STARband Cranial Remolding Orthosis - K082950 to proposed device: The Boston Band

Note: No changes will be made to the current device as a result of the proposed indications and shape capture change in this submission

Feature	Predicate Device (K082950)	The Boston Band
Intended Use	The STARband is intended for medical purposes for use on infants from three to eighteen months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and /or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected but who still have moderate to severe cranial deformities including plagiocephalic brachycephalic and scaphocphalic shaper heads	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Materials	- outer shell of .156 copoly plsitc) - An inner liner of ½" pelite polyethylene foam or ½ Aliplast - Strap of 1 ½" Dacron - A 1 ½ " chafe buckle - Large Flange,Blind Rivet - A Gap Block made from ½' firm pelite polyethylene foam - A nylon washer	- outer shell of thermoformable plastic (1/4 or 3/16 copolymer plastic) - a single layer of ½ inch or 5-6 layers of 1/8 inch, or a combination of 1 – 2 1/4 inch layers with 1/8 inch layers of pelite hypoallergenic polyethylene foam or Aliplast - Velcro strap (pile) sticky back Velcro hook
Product Design	Cranial orthosis - made to individual's specifications – approx 6 oz in weight	Cranial orthosis –made to individual's specifications
Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster case - The 3-ddimensional image is used to produce a positive mold using 5-axis routing machine	Model of the infants head from a negative impression (cast) of the infants head -Scan of the infants head from a Fastscan hands free class II laser scanner -Scan of the infants head using a Fastscan handheld class I laser scanner - Scan of the infants head using the Creaform class I laser scanner sold as Ohio Willow Wood Omega/handycam - Foam model of the infants head carved using an industry standard 5 axis scanner

Table 4 Comparison of STARband Cranial Remolding Orthosis - K082950 to proposed device: The Boston Band

Labeling	Predicate Device (K082950)	The Boston Band
Indications	The STARband is intended for medical purposes for use on infants from three to eighteen months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and /or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected but who still have moderate to severe cranial deformities including plagiocephalic brachycephalic and scaphocphalic shaper heads	Same and to include the adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic, brachycephalic, and scaphocephalic shaped heads.
Contraindications	Infants with Craniosynostosis or hydrocephalus	Same
Warnings	Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of growth. Describe to caregiver steps that should be taken to reduce the potential restrictions of cranial growth and possible impairments to brain growth and development. A clinician or caregiver must evaluate the patient's skin at frequent intervals.	Same
Precautions	If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit it according to fitting instructions. Wear and care guide to be reviewed and provided to caregiver.(copy attached)	Same
Adverse Effects	This device may cause skin irritations or breakdown	Same
Instructions for Use	Wear and care guide provided to caregiver	Same
Expiration date	When the infant outgrows the cranial helmet or the orthosis is discontinued for any reason, the referring physician is contacted. If an other helmet is requested by the family to try to further correction, refer back to their physician for reevaluation and a new prescription.	Same

Table 5 Comparison of Hanger Cranial Band (K072566) to proposed device: The Boston Band

Note: No changes will be made to the current device as a result of the proposed indications and shape capture change in this submission

Feature	Predicate Device K072566	The Boston Band
Intended Use	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes.	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Materials	- outer shell of thermoformable plastic - hypoallergenic polyethylene foam - Velcro strap (pile) sticky back Velcro hook	- outer shell of thermoformable plastic (1/4 or 3/16 copolymer plastic) - a single layer of ½ inch or 5-6 layers of 1/8 inch, or a combination of 1 – 2 1/4 inch layers with 1/8 inch layers of hypoallergenic polyethylene foam - Velcro strap (pile) sticky back Velcro hook
Product Design	Cranial Orthosis –made to individual's specifications	Cranial Orthosis –made to individual's specifications
Production	- -Scan of the infants head from a Fastscan hands free class II laser scanner - Foam model of the infants head carved using an industry standard 5 axis scanner	Model of the infants head from a negative impression (cast) of the infants head -Scan of the infants head from a Fastscan hands free class II laser scanner -Scan of the infants head using a Fastscan handheld class I laser scanner - Scan of the infants head using the Creaform class I laser scanner sold as Ohio Willow Wood Omega/handycam - Foam model of the infants head carved using an industry standard 5 axis scanner

Table 6 Comparison of Hanger Cranial Band (K072566) to proposed device: The Boston Band

Labeling	Predicate Device K072566	The Boston Band
Indications	Intended for medical purposes to apply static or gentle pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Contraindications	Infants with Craniosynostosis or hydrocephalus	Same
Warnings	Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of growth. Describe to caregiver steps that should be taken to reduce the potential restrictions of cranial growth and possible impairments to brain growth and development. A clinician or caregiver must evaluate the patient's skin at frequent intervals.	Same
Precautions	If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit it according to fitting instructions. Wear and care guide to be reviewed and provided to caregiver.(copy attached)	Same
Adverse Effects	This device may cause skin irritations or breakdown	Same
Instructions for Use	Wear and care guide provided to caregiver	Same
Expiration date	When the infant outgrows the cranial helmet or the orthosis is discontinued for any reason, the referring physician is contacted. If an other helmet is requested by the family to try to further correction, refer back to their physician for reevaluation and a new prescription.	Same

7) **Summary and Conclusions of Non-Clinical Performance Data**

The Boston Band Cranial Remolding Orthosis has been marketed in the US since its original clearance in 2007. Since that time advances have been made in surgical techniques to treat craniosynostosis, scanning technologies, computer aided design (CAD) software, and multi-axis carves.

The Fastscan hands free class II laser scanner was cleared in K072862. Fastscan now offers hands free class I laser scanner. With the laser scanners the safety issue is the class of laser. Like the predicate device (K082950), this class I laser is inherently safe for use without eye protection under all normal operating conditions. The effectiveness of this scanning device was evaluated through accuracy and repeatability testing. Positive foam models were scanned using the Fastscan hands free class I laser scanner. The scanned models were then carved and measured to compare to the original model. Each device met the predetermined acceptance criteria and was found acceptable.

Rodin4D CADCAM software (http://www.rodin4d.com/en) is a 3D rectification software for manufacturing orthopedic devices. Currently carved positive models are modified by hand according to the needs of the patient. The software has now developed to where these modifications can be done in CAD. The original scanned model is saved and each step of modification is recorded in the software. The modifications are still to the needs of the patient and follow the same steps as if done by hand. The difference is that each step is now saved in the software. The effectiveness of this modification software was evaluated through accuracy and repeatability testing. A comparison was made between hand modified and Rodin4D modifications of the same models. Four models were selected. Hand modifications were done on carved models and CAD modifications were done on the electronic models. The electronic models were then carved. All models where then measured and compared. The results showed that both modification techniques produced an acceptable modified model for fabrication. Practitioners having CAD software will have the ability to modify the model electronically according to the needs of the patient.

Since the time of the predicated device approval (K072862) the 3-axis carver has been upgraded to remain current with carving machinery. The only major change is the speed of carving.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Brace International, Inc.
c/o James H. Wynne
Vice President, Direction of Education
20 Ledin Drive
Avon, MA 02322

AUG 2 2 2011

Re: K111609
Trade/Device Name: Boston Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: May 24, 2011
Received: June 9, 2011

Dear Mr. Wynne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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20 Ledin Drive
Avon, MA 02322
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F: 508.587.8119
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Indications for Use Statement

510(k) Number (if known): K111609

Device Name: Boston Band

Indications for Use:

The Boston Band is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial proportion and symmetry in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111609